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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Plaintiffs, v. EAGLE PHARMACEUTICALS INC., Defendant.	Case No. 3:20-cv-18319 (BRM-DEA) *Confidential* *Electronically Filed Under Seal*

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT EAGLE PHARMACEUTICALS, INC.'S
MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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I. INTRODUCTION

The Court should dismiss Par's Amended Complaint because Par does not accuse Eagle's current ANDA of infringement, but rather speculates that infringement might occur in the future ***if*** the FDA approves Par's requested label change and ***if*** the FDA also requires Eagle to make the same change.[1]

Specifically, Par's infringement claims under § 271(e)(2) cannot stand because a "patented method of using a drug ***can only be infringed under § 271(e)(2)*** by filing an ANDA that seeks approval to market the drug for that use." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012) (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358–59 (Fed. Cir. 2003)) (emphasis added). U.S. Patent No. 10,844,435 (the "'435 patent") claims a method for treating **septic shock patients** having one of two specific genotypes (AA or AT) "wherein the maximum dose is ***0.085 units/minute***." (D.I. 22, Ex. A ('435 Patent), cl. 1 (emphasis added).) U.S. Patent No. 10,920,278 (the "'278 patent") claims a method for treating **post-cardiotomy shock patients** having one of two specific genotypes (AA or AT) "wherein the maximum dose is ***0.121 units/minute***." (D.I. 22, Ex. B ('278 Patent), cl. 1 (emphasis added).) [redacted]

Likewise, Par's § 271(b) claims cannot stand because they require an "explicit direction or instruction by [Eagle] that would lead to active infringement." *Novartis Pharm., Corp. v.*

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[1] Indeed, Par cannot accuse Eagle's proposed ANDA of infringement, because [redacted]

Wockhardt USA LLC, No. 12-cv-3967, 2013 WL 5770539, at *9 (D.N.J. Oct. 23, 2013). [redacted]

Par attempts to fix these flaws by speculatively alleging that at some time in the future the FDA will (1) approve a change to ***Par's*** label for VASOSTRICT® to allow for treatment of patients with AA or AT genotypes up to 0.085 units/minute for septic shock and 0.121 units/minute for post-cardiotomy shock, and then (2) subsequently require ***Eagle's*** proposed label in its ANDA be amended in the same way. (D.I. 22 ¶¶ 38, 42.) But complaints that "rely on prospective labeling amendments … rest on contingent future events that may never occur," and therefore are unripe and must be dismissed. *AstraZeneca*, 669 F.3d at 1381.

Par's claims are premised "on the mistaken belief that the Court can and should determine patent infringement by looking to drug formulations and ANDAs not yet in existence." *Par Pharm., Inc. v. Luitpold Pharm., Inc.*, No. 16-cv-2290, 2017 WL 452003, at *6 (D.N.J. Feb. 2, 2017). The Court should dismiss the Amended Complaint in its entirety.[2]

II. FACTUAL BACKGROUND

Par holds approved New Drug Application ("NDA") No. 204485 for the brand drug VASOSTRICT®. (D.I. 22 ¶¶ 17–18.) The FDA approved Par's original VASOSTRICT® product in 2014. (*Id.*) The active ingredient in VASOSTRICT® is the drug vasopressin. (*Id.* ¶ 19.) Vasopressin "causes contraction of vascular and smooth muscle cells" and is commonly used to "increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis)." (*Id.*

[2] On March 1, 2021, Eagle filed a motion to dismiss Par's initial complaint. The Court administratively terminated Eagle's motion on March 4, 2021. (D.I. 12.) On March 22, 2021, Par filed its Amended Complaint (D.I. 22) which this motion to dismiss addresses.

¶¶ 19–20.) According to the FDA-approved label, the maximum dosage of VASOSTRICT® is 0.07 units/minute for a patient in septic shock and 0.1 units/minute for a patient in post-cardiotomy shock. (*Id*. at Ex. D at 2.)

In 2018, Eagle filed an Abbreviated New Drug Application ("ANDA") No. 211538 with the FDA seeking approval to market a generic version of [redacted] VASOSTRICT® product.[3] [redacted] Eagle's ANDA has not yet been approved by the FDA.

Several years after Eagle filed its ANDA, the '435 patent and '278 patent (collectively, the "Patents in Suit") issued. The Patents in Suit claim substantially similar methods for treating patients in shock having one of two specific genotypes (AA or AT).

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[3] After Eagle filed ANDA No. 211538, Par brought suit in the District of Delaware, alleging infringement of six patents. *See Par Pharm., Inc. v. Eagle Pharm., Inc.*, Case No. 1-18-cv-00823 (D. Del.). Par subsequently dropped four patents from the suit, and the litigation is ongoing with respect to the remaining two patents.

[4] Eagle's confidential proposed ANDA label is "'integral to or explicitly relied upon in the complaint'" and thus "may be considered 'without converting the motion [to dismiss] into one for summary judgment.'" *Borough of Moosic v. Darwin Nat'l Assurance Co.*, 556 F. App'x 92, 95 (3d Cir. 2014) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)). For example, Par makes allegations relating to Eagle's proposed ANDA label. (*See, e.g.*, D.I. 1 ¶¶ 38, 42, 57.) Similarly, Par's claim of infringement under 35 U.S.C. § 271(e)(2) necessarily depends on Eagle's confidential proposed ANDA label. *See AstraZeneca*, 669 F.3d at 1379.

Neither of the Patents in Suit claim the FDA-approved method of use for VASOSTRICT®, [redacted]. (*See* D.I. 22 ¶ 38, Ex. D at 2.) Instead, the Patents in Suit claim a method of administering a higher dose of vasopressin (0.085 units/minute and 0.121 units/minute) to those patients having AA or AT genotypes. (*Id*.) Claim 1 of the '435 patent recites:

> A method of increasing blood pressure to a target blood pressure in a human patient ***with septic shock wherein the patient has an LNPEP AA or AT rs4869317 genotype***, the method comprising: intravenously administering to the patient a pharmaceutical formulation comprising vasopressin at a starting dose of 0.01 units/minute and titrating the dose up by 0.005 units/minute at 10 to 15 minute intervals to maintain the target blood pressure, ***wherein the maximum dose is 0.085 units/minute***.

(D.I. 22, Ex. A, cl. 1) (emphasis added). Claim 1 of the '278 patent recites:

> A method of increasing blood pressure to a target blood pressure in a human patient ***with post-cardiotomy shock wherein the patient has an LNPEP AA or AT rs4869317 genotype***, the method comprising: intravenously administering to the patient a pharmaceutical formulation comprising vasopressin at a ***starting dose of 0.03 units/minute*** and titrating the dose up by 0.005 units/minute at 10 to 15 minute intervals to maintain the target blood pressure, ***wherein the maximum dose is 0.121 units/minute*** .

(D.I. 22, Ex. B, cl. 1) (emphasis added). [redacted]

Claim 1 of the '435 Patent and claim 1 of the '278 Patent are nearly identical. The table below shows these claims side-by-side, with the differences highlighted:

Claim 1 of the '435 Patent	Claim 1 of the '278 Patent
A method of increasing blood pressure to a target blood pressure in a human patient with ***septic shock*** wherein the patient has an LNPEP AA or AT rs4869317 genotype, the method comprising: intravenously administering to the patient a pharmaceutical formulation comprising vasopressin at a ***starting dose of 0.01 units/minute*** and titrating the dose up by 0.005 units/minute at 10 to 15 minute intervals to maintain the target blood pressure, wherein ***the maximum dose is 0.085 units/minute***.	A method of increasing blood pressure to a target blood pressure in a human patient with ***post-cardiotomy shock*** wherein the patient has an LNPEP AA or AT rs4869317 genotype, the method comprising: intravenously administering to the patient a pharmaceutical formulation comprising vasopressin at a ***starting dose of 0.03 units/minute*** and titrating the dose up by 0.005 units/minute at 10 to 15 minute intervals to maintain the target blood pressure, wherein ***the maximum dose is 0.121 units/minute*** .

(D.I. 22, Ex. A, cl. 1, Ex. B, cl. 1) (emphasis added).

In December 2020, Par submitted a request to the FDA to amend "the current label for VASOSTRICT®, in order to include new instructions concerning the dosage and administration of VASOSTRICT® … to patients with AA or AT genotypes." (D.I. 22 ¶ 38, Ex. D.) For septic shock patients, Par's proposed amendment specifies the higher maximum dose of 0.085 units/minute for those patients with genotypes AA or AT. For post-cardiotomy shock patients, Par's proposed amendment specifies the higher maximum dose of 0.121 units/minute for those patients with genotypes AA or AT. The FDA has not approved Par's request to amend the current VASOSTRICT® label. (*Id.* ¶ 38.) It is not known whether the FDA will or will not approve the amendment.

III. LEGAL STANDARDS

To survive a motion to dismiss under FED. R. CIV. P. 12(b)(6), Par's Complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Par's "complaint must do more than allege [its] entitlement to relief;" it must

"'show' such an entitlement with its facts." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009).

For a patent infringement claim under 35 U.S.C. § 271(e)(2), Par must "show that: 1) the alleged infringer submitted an ANDA; 2) the ANDA was for a drug claimed in a patent or the use of which was claimed in a patent; and 3) the purpose of the ANDA must have been to obtain approval for the commercial manufacture, sale, or use of the drug before the expiration of such patent." *Eisai Co. v. Mutual Pharm. Co.*, No. 06-cv-03613, 2007 WL 4556958, at *9 (D.N.J. Dec. 20, 2007). "[T]he burden is on [Par] to prove that each and every limitation of the patent as construed is found in the accused [ANDA]." *Organon, Inc. v. Teva Pharm., Inc.*, 244 F. Supp. 2d 370, 377 (D.N.J. 2002) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1565 (Fed. Cir. 1997)).

Par's claims for relief under 35 U.S.C. § 271(b) requests that the Court grant declaratory judgment that Eagle will induce infringement of the '435 patent (D.I. 22 ¶ 68) and '278 patent. (*Id.* ¶ 84.) "The availability of declaratory relief is limited [] by Article III of the Constitution, which restricts judicial power to the adjudication of 'Cases" or "Controversies.'" *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008). In a motion to dismiss for lack of subject matter jurisdiction under FED. R. CIV. P. 12(b)(1), "[t]he burden is on [Par] to prove that subject matter [jurisdiction] exists." *Novo Nordisk Inc. v. Mylan Pharm. Inc.*, No. 09-cv-02445, 2010 WL 1372437, at *5 (D.N.J. Mar. 31, 2010). Par must show that the facts alleged support a finding that there is a "substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1345 (Fed. Cir. 2010) (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)).

To satisfy the "immediacy and reality" prong of the inquiry, Par must show "(1) an injury-in-fact, *i.e.*, a harm that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical,' (2) that is 'fairly traceable' to the defendant's conduct, and (3) redressable by a favorable decision." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008) (internal quotations omitted). Moreover, "no presumption of truthfulness attaches to the allegations in [Par's] complaint." *Hoffman-La Roche, Inc. v. Genpharm Inc.*, 50 F. Supp. 2d 367, 372 (D.N.J. 1999) (citing *Mortensen v. First Fed. Savings & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977)).

IV. ARGUMENT

A. Par's Claims Under 35 U.S.C. § 271(e)(2) Must Be Dismissed Because Par Fails to State A Claim Upon Which Relief May Be Granted

1. The Accused Eagle ANDA Does Not Seek Approval For The Method Of The Patents in Suit

The Court should dismiss Par's § 271(e)(2) claims in Counts I and III of the Amended Complaint because Par does not allege that Eagle's ANDA seeks approval to market its vasopressin product for the uses specified in the Patents in Suit. To infringe a patent under § 271(e)(2), the submitted ANDA must seek FDA approval to market the drug or the use claimed in a patent. *Warner-Lambert*, 316 F.3d at 1354–55 & 1358–62; *see also AstraZeneca*, 669 F.3d at 1379 ("[A] patented method of using a drug ***can only be infringed under § 271(e)(2)*** by filing an ANDA that seeks approval to market the drug for that use." (emphasis added)) (citing *Warner-Lambert*, 316 F.3d at 1358–59). In *Warner-Lambert*, the plaintiff obtained approval of an NDA to market a drug for a specific use and the generic manufacturer filed an ANDA "seeking approval to market a generic formulation … only for the same indication" as the patent owner. 316 F.3d at 1352. The plaintiff sued the generic manufacturer for infringement of a patent claiming different methods of use than those approved by the FDA. *Id.* Affirming the district court's grant of summary judgment, the Federal Circuit explained that the plaintiff did "not have a cause of action

under § 271(e)(2)(A)" because the generic manufacturer did not "submit[] an application to sell a drug the use of which is claimed in an extant patent." *Id*. at 1362.

Warner-Lambert is indistinguishable and compels dismissal. The '435 patent claims a method of "administering … vasopressin … wherein the maximum dose is ***0.085 units/minute***" for "a human patient with septic shock … [and an] AA or AT … genotype." (D.I. 22, Ex. A at cl. 1 (emphasis added).) The '278 patent claims a method of "administering … vasopressin … wherein the maximum dose is ***0.121 units/minute***" for "a human patient with post-cardiotomy shock … [and an] AA or AT … genotype." (D.I. 22, Ex. B at cl. 1 (emphasis added).) To infringe, Par must "prove that the accused [ANDA] contains each limitation of the asserted claim(s)." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). [redacted] Indeed, Par seemingly acknowledges that Eagle's proposed ANDA does not infringe by speculating that Eagle will have to "amend the proposed labeling." (D.I. 22, ¶¶ 42–43.)

Thus, Eagle's "ANDA does not infringe the Patents in Suit as its [use] falls outside the [] claims of the [Patents in Suit]." *Par Pharm.*, 2017 WL 452003, at *6.

2. Par's Claims Based On An Amended Label Are Not Ripe

Par's argument that Eagle's ANDA will infringe in the future if Eagle is required to amend its label is not ripe and cannot save Par's § 271(e)(2) claim. A claim is unripe "if it rests upon ***contingent future events*** that ***may not occur as anticipated***, or indeed ***may not occur at all***." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotations omitted). Section 271(e)(2)

claims "based on presumed future labeling amendments are unripe" and should be dismissed. *AstraZeneca*, 669 F.3d at 1381. In *AstraZeneca*, the generic manufacturer did not seek approval for the "patented indications." *Id*. at 1374. Nonetheless, the patentee there "alleged that the FDA will require [the accused generic manufacturers] to amend their ANDAs at some unspecified point in the future to include all FDA-approved indications for [the drug], including those covered by the ... patents, resulting in infringement under § 271(e)(2)." *Id*. at 1380. The Federal Circuit rejected this argument as speculative and affirmed dismissal.

Par itself has previously attempted this same argument in this Court, unsuccessfully, in *Par Pharm., Inc. v. Luitpold Pharm., Inc.*, 2017 WL 452003. There, the accused ANDA product "d[id] not infringe Par's patents," *id.* at *5, but Par contended that the defendant "will have to amend its ANDA in order to obtain FDA approval," and that this amended ANDA would infringe. *Id*. at *4, *6 (internal quotations omitted). The Court rejected Par's argument: "Because Par's claim is entirely premised on speculation that future, uncertain amendments to [the generic manufacturer's] ANDA will infringe Par's patents, and there is no question that the drug specified in [the generic manufacturer's] ANDA does not infringe the Patents-in-Suit, judgment in favor of [the generic manufacturer] is warranted." *Id*. at *6.

The same reasoning requires dismissal here. Eagle's ANDA indisputably does not "seek[] approval for activities that would constitute infringement" of the '435 patent or '278 patent. *AstraZeneca*, 669 F.3d at 1381. Par's argument that the FDA will require Eagle "as a matter of law to amend the proposed labeling for its Proposed ANDA Product" is speculative, as it was in *AstraZeneca*. (D.I. 22 ¶ 42.)

The Hatch-Waxman Act "permits generic manufacturers to file ANDAs directed to a subset of FDA-approved indications and even provides a mechanism for ANDA applicants to

affirmatively carve out patented indications by submitting Section viii statements." *AstraZeneca*, 669 F.3d at 1381. While Par's Amended Complaint alleges that the FDA will refuse to approve Eagle's ANDA without amended instructions, this is a flawed and speculative legal conclusion. (*See* D.I. 22 ¶ 42.) The Code of Federal Regulations expressly allows for ANDA approval where differences between the ANDA and the listed drug exist "because aspects of the listed drug's labeling are protected by patent … and such differences do not render the proposed drug product less safe or effective than the listed drug." 21 C.F.R. § 314.127(a)(7). Par has not and cannot establish that the FDA will approve Par's requested amendment, that the FDA will require Eagle's ANDA to include Par's proposed amended instructions, or that Eagle's ANDA would be less safe or less effective without Par's amended instructions. And whether or not the FDA must refuse to approve Eagle's ANDA without amended instructions is a "legal conclusion couched as a factual allegation" that this Court is "not bound to accept as true" at this stage, particularly when Par's request for amendment is still under consideration. *Bell Atl.*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Furthermore, Par previously conceded that the "FDA [could] approve Eagle's ANDA without those [amended] instructions included in the labeling for the Proposed ANDA Product." (D.I. 1 ¶ 42.) And even Par's Amended Complaint acknowledges this possibility, alleging that "Eagle's Proposed ANDA Product ***is likely*** to include" Par's amended labeling information. (D.I. 22 ¶ 46.) Therefore, like *AstraZeneca*, "nothing in the record indicates that the FDA [will] require[] [Eagle] to add further indications" or instructions to its label. 669 F.3d at 1381. In fact, this case is even more speculative than *AstraZeneca*. Here, the FDA has not even approved ***Par's*** requested label change, let alone asked ***Eagle*** to amend its label.

3. Par Cannot Allege Inducement Of § 271(e)(2) Infringement

Par's attempt to argue inducement of § 271(e)(2) infringement, (D.I. 22 ¶¶ 55, 71), fares no better. Par's Complaint alleges that *if* the FDA requires Eagle to amend its ANDA labeling, then Eagle's ANDA would induce infringement of the Patents in Suit because, "***if*** Eagle were to obtain FDA approval to market and sell its Proposed ANDA Product, it would market and sell it to hospitals and/or group purchasing organizations ('GPOs') and other distributors … as a generic substitute for VASOSTRICT® to be used and administered in the same manner as VASOSTRICT®." (D.I. 22 ¶ 44 (emphasis added).) Par further alleges that "Eagle's sales force will make affirmative representations to its customers that Eagle's ANDA Product is equivalent to VASOSTRICT® and can and should be administered in the same manner as VASOSTRICT®" and "the proposed labeling for Eagle's Proposed ANDA Product is ***likely*** to include specific instructions directing physicians and other medical professionals to use the product to treat patients with AA or AT genotypes." (*Id*. ¶¶ 45, 46 (emphasis added).) But, as with its direct infringement allegations, these inducement allegations turns on Par's speculation about Par's label amendment being approved and the FDA requiring Eagle to adopt the same label. *See AstraZeneca*, 669 F.3d at 1375, 1380–81.

Par also contends that "Eagle will nevertheless induce infringement of the Patents in Suit in ways beyond just the instructions included on the label." (D.I. 22 ¶ 47.) In other words, Par speculates that physicians would use Eagle's vasopressin product off-label, if the FDA approves Eagle's ANDA label without Par's proposed instructions. But Par cannot make a claim for induced infringement under § 271(e)(2) based on speculative off-label use. *See AstraZeneca*, 669 F.3d at 1381. As the Federal Circuit has made clear, this argument "is not cognizable under [35 U.S.C. §] 271(e)(2)." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1324 (Fed. Cir. 2003). Indeed, Par "is precluded from suing [Eagle] under section 271(e)(2) for inducing infringement of the

[Patents in Suit], because [Eagle is] not seeking FDA approval for the uses claimed in the patents and because the uses claimed in the patents are not FDA-approved." *Id.* at 1334. "Because the product that can be manufactured under [Eagle's] ANDA does not infringe Par's patents, [Eagle's] motion [to dismiss should be] granted." *Par*, 2017 WL 452003, at *5.

B. Par's Claims Under 35 U.S.C. § 271(b) Must Be Dismissed Because This Court Lacks Subject Matter Jurisdiction and Par Fails to State A Claim Upon Which Relief May Be Granted

1. This Court Lacks Subject Matter Jurisdiction Over Par's Claims For Relief Under § 271(b)

The Court should dismiss Par's claims under § 271(b), Counts II and IV of the Amended Complaint, because there is no subject matter jurisdiction. Par is "seeking to establish declaratory judgment jurisdiction[, so it] bears the burden of demonstrating that an Article III case or controversy exists at the time the claim for declaratory relief is filed." *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1328 (Fed. Cir. 2012). To present an actual case or controversy, Par must show that "'the facts alleged, under all the circumstances, show that there is a substantial controversy … of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014). Par fails to do so here.

Par cannot meet its burden to establish either "reality" or "immediacy." Par's Amended Complaint does not allege that Eagle is ***currently*** "actively induc[ing] infringement" of either Patent in Suit, only that it "might some day." *IGI Labs., Inc. v. Mallinckrodt LLC*, No. 13-cv-02044, 2014 WL 1652790, at *1 (D. Del. Apr. 22, 2014). As discussed above, Par's claims depend on multiple layers of speculation. Par speculates that the FDA will approve Par's request to amend the VASOSTRICT® label "to include new instructions concerning the dosage and administration of VASOSTRICT® … to patients with AA or AT genotypes." (D.I. 22 ¶ 38.) Par then speculates

that Eagle ***may*** be required to "amend the proposed labeling for its Proposed ANDA Product" to "include … the same instructions for treating patients with the AA or AT genotypes" in order to obtain FDA approval. (*Id.* ¶¶ 42–43.) But as noted, it is unclear whether the FDA will approve Par's amendment, and even if so, unclear whether the FDA would require Eagle to amend its proposed label in order to obtain FDA approval.

Thus, Par's claims, which, at best, allege "fluid and indeterminate" circumstances regarding the accused product, "fail[] to meet constitutionally-mandated reality requirements." *Matthews*. 695 F.3d at 1330 (citing *Cat Tech*, 528 F.3d at 882). "The greater the variability of the subject of a declaratory-judgment suit, particularly as to its potentially infringing features, the greater the chance that the court's judgment will be purely advisory, detached from the eventual, actual content of that subject—in short, detached from eventual reality." *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004). "Simply put, because [the FDA's ultimate determinations on Par's and Eagle's respective applications] are unknown, any judicial determination as to whether [Eagle's generic vasopressin] could infringe [the Patents in Suit] would constitute an advisory opinion based upon a hypothetical set of facts." *Matthews*. 695 F.3d at 1331 (citing *Arctic Corner, Inc. v. U.S.*, 845 F.2d 999, 1000 (Fed. Cir. 1988)).

Likewise, Par's speculative allegations fail the "immediacy" requirement. Par's claims "lack[] immediacy because there is no evidence as to when, if ever, [Eagle's generic vasopressin] will be used in a manner that could potentially infringe the" Patents in Suit. *Id.* at 1328. Moreover, Par pleads no facts supporting the conclusion that the events about which it speculates will occur any time in the near future and "the greater the length of time before potentially infringing activity is expected to occur, the more likely the case lacks the requisite immediacy." *Id.* at 1330 (citing *Cat Tech*, 528 F.3d at 881).

Because Par's § 271(b) declaratory judgment claim "lacks the requisite immediacy and reality to support the exercise of declaratory judgment jurisdiction," it should be dismissed for lack of subject matter jurisdiction. *Id*. at 1328.

2. Par's § 271(b) Claim Must Be Dismissed Because Par Fails to State a Claim Upon Which Relief May Be Granted

Even if the Court has jurisdiction, it should dismiss Par's § 271(b) claim. To survive a motion to dismiss, Par has to plead facts that could establish "that [Eagle's] actions induced infringing acts and that [Eagle] knew or should have known [its] actions would induce actual infringement." *Warner-Lambert*, 316 F.3d at 1363 (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 533 (Fed. Cir. 1990)) (internal quotations omitted). Par can prove neither.

Par does not even allege that Eagle has asked the FDA for a label that would permit infringement. *See Novartis*, 2013 WL 5770539, at *8 (citing *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1999)). "Section 271(b) imposes liability on those who 'actively induce[] infringement,' not on those who might some day induce infringement." *IGI*, 2014 WL 1652790, at *1 (alteration in original). As Par previously conceded, the FDA may "approve Eagle's ANDA without [Par's proposed] instructions included." (D.I. 1 ¶ 42.) And here Par alleges that "Eagle's Proposed ANDA Product is likely to include" Par's proposed amended instructions. (D.I. 22 ¶ 46.) Consequently, Par's claim is not ripe because the "contingent future events" Par hinges its claim on "may not occur as anticipated, or indeed may not occur at all." *Texas*, 523 U.S. at 300.

Further, even if Par's requested amendment were already approved (which it is not), Par's inducement claim would still need to be dismissed because a key element of inducement is "actual intent to cause the acts which constitute the infringement." *Novartis*, 2013 WL 5770539, at *8 (citing *Hewlett-Packard*, 909 F.2d at 1469). But Par's Complaint does not identify any

"affirmative steps taken to foster infringement" by Eagle that would lead it to be "liable for the resulting acts of infringement by third parties." *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1305–06 (Fed. Cir. 2006); *see also*, *Novartis*, 2013 WL 5770539, at *9. Indeed, Courts have found no intent where, like Par's claim, the "ANDA[] seek[s] approval only for [a non-infringing use] and [its] proposed label[] [does] not mention [the claimed use]." *Novartis*, 2013 WL 5770539, at *9. The "mere knowledge of possible infringement by others does not amount to inducement." *Warner-Lambert*, 316 F.3d at 1364. Par's allegation of a mere possibility that some day in the future the FDA will require Eagle to amend its label is not sufficient to establish that Eagle knows now that its ANDA will induce infringement.

Par's speculation that "Eagle's sales force will make affirmative representations to its customers that Eagle's ANDA Product is equivalent to VASOSTRICT® and can and should be administered in the same manner as VASOSTRICT®" cannot save its claims. (D.I. 22 ¶ 45.) Eagle is not marketing its Proposed ANDA Product—it has not been approved yet—and Par's speculation as to "[h]ypothetical instances" of conduct that may occur in the future are not sufficient to create a ripe dispute. *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007). Par's speculation that "the proposed labeling for Eagle's Proposed ANDA Product is likely to include specific instructions directing physicians" to practice the claimed methods is similarly inadequate, as it again relies on the unfounded assumption that Eagle's Proposed ANDA Label will include Par's proposed instructions. (D.I. 22 ¶ 46.) As to Par's allegation that any usage of Eagle's Proposed ANDA Product "in the same manner as VASOSTRICT®" would constitute inducement, Par ignores that this drug has been in use for over 100 years and using consistent with that precedent cannot constitute inducement. (D.I. 22 ¶ 44);

Novartis, 2013 WL 5770539, at *9 (holding "Plaintiffs 'market realities' arguments [] not sufficient to establish intent to induce infringement").

As discussed above, allegations dependent on speculative and uncertain future events simply cannot establish a ripe case and controversy. *See AstraZeneca*, 669 F.3d at 1381.

V. CONCLUSION

For the reasons set forth above, Par's Amended Complaint against Eagle should be dismissed.

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Respectfully submitted,

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